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ACCESS AND RATIONAL USE OF STRATEGIC AND HIGH-COST MEDICINES AND OTHER HEALTH TECHNOLOGIES

Introduction

1. Equitable access to medicines and other health technologies is a requisite for universal access to health and universal health coverage and it is a global priority which should be considered within the context of the importance of the right to the enjoyment of the highest attainable standard of health for all and the recognition that this right has received.[1] The availability, accessibility, acceptability, and affordability of these medical products and their rational use can be facilitated through the adoption of comprehensive policies, legal and regulatory frameworks, and interventions. The escalating costs of providing access to high-cost medical products, however, pose a particular challenge for the sustainability of health systems.

2. This document provides a comprehensive overview of the multidimensional problem of access to high-cost medicines and other health technologies.[2] It also identifies policy options that can safeguard the sustainability of health systems and expand access to high-cost strategic products to improve health outcomes.

Background

3. In 2014, the Region adopted Resolution CD53.R14, Strategy for Universal Access to Health and Universal Health Coverage. This strategy aims at ensuring that all people and communities have access, without any kind of discrimination, to comprehensive, appropriate, and timely quality health services determined at the national level according to needs, as well as access to safe, affordable, effective, quality medicines, while

[1] The Constitution of the World Health Organization establishes as a principle that the enjoyment of the highest attainable standard of health is one of the fundamental human rights of every human being. The Constitution was adopted by the International Health Conference, New York, signed on 22 July 1946 by 61 Member States and subsequently ratified by 194 Member States. See also, for example, Pan American Sanitary Conference Document CSP28/11 "Health Technology Assessment and Incorporation into Health Systems," page 2.

[2] For the purpose of this document, medicines and other health technologies include medical products such as pharmaceuticals, biologicals, medical devices, and diagnostics.

protecting them from financial hardship, especially groups in conditions of vulnerability. In 2015, the United Nations General Assembly adopted 17 Sustainable Development Goals. Goal 3, Ensure healthy lives and promote well-being for all at all ages, includes targets on equitable access to medicines and other health technologies.

4. For Member States, ensuring access to safe, efficacious, and quality medicines and other health technologies has remained a high priority. In 2004, countries adopted Resolution CD45.R7, Access to Medicines, highlighting the need to improve quality, financing, procurement, cost-containment, intellectual property management, and supply management of medicines. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (Resolution WHA61.21 [2008]) *(1)* and the corresponding PAHO plan of action (Resolution CD48.R15 [2008]) encourage the adoption of comprehensive frameworks to promote access to medicines and other health technologies. Resolution CD50.R9, adopted in 2010, called for the strengthening of regulatory capacity to ensure safe, efficacious, and quality medicines *(2)*. The value of Health Technology Assessment (HTA) and other evidence-based approaches that weigh ethical considerations to guide and inform prioritization and selection of products is reflected in Resolution CSP28.R9 *(3)* and Resolution WHA67.23 *(4)*. A number of resolutions to address critical communicable and noncommunicable diseases (NCDs) highlight the need to improve access to medicines and other health technologies. Notably, the Plan of Action for the Prevention and Control of Noncommunicable Diseases (Resolution CD52.R9 [2013]) emphasizes the need to improve access to medicines and health technologies for NCDs. Regarding access to medicines and other technology related laws and regulations, the Directing Council of PAHO has urged Member States, as appropriate, to promote the formulation, implementation or review of their legal and regulatory frameworks to facilitate the strengthening of the stewardship and governance role of the health authority to move toward achieving universal access to quality, safe, effective and affordable medicines and other health technologies *(5)*.

5. Essential medicines are those that satisfy the priority health care needs of the population and should be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford. The WHO Model list of Essential Medicines (EML) is a model reference list containing a majority of affordable and cost-effective products that can significantly contribute to positive health outcomes *(6, 7)*. In addition, increasing numbers of other strategic health technologies such as medical devices have become critical for preventive, curative, rehabilitative, and palliative care. Offering a broader number of medicines, beyond those listed in the WHO EML, may reflect the specific context and/or the capacity of some countries to provide access to other products, including new and costly ones. Moreover, the adoption of integrated strategies for rational use, such as that adopted by the Meeting of the Ministers of Health of the Andean Region in 2015, which includes clinical practice guidelines (CPGs), incentives, prescription support, and educational strategies, among others, has been shown to improve health outcomes *(8-11)*.

6. A number of new products can meaningfully contribute to improving health. The 19th WHO EML (April 2015) includes several new high-cost medicines both for communicable and noncommunicable diseases. However, not all new molecules provide substantial value; new high-cost medicines may offer only marginal health gains over older lower-cost medicines. It is noteworthy that the concept of high cost is not well defined. While a distinction must be made between price and affordability,[3] some countries have chosen to define high cost by the monetary value of treatment (threshold) while for others, it is a relative term based on costs that are disproportionate with respect to expected costs of treatment. Nonetheless, prices are not the sole determinant of cost since both the frequency and length of treatment impact the overall cost of medical products, and prices are not uniform across countries due to: manufacturers' pricing strategies; variable distribution; intermediary and retail markups; and variable national taxes and duties imposed on medical products *(12).* Still, products comprised within the high-cost category generally include new pharmaceuticals, biologicals including vaccines, devices and other health technologies produced and commercialized by a single manufacturer (i.e. sole-source products) and, due to patent protection, retain market exclusivity, do not face competition, and tend to follow monopolistic pricing rules *(13).*

7. Providing access to high-cost medicines is a cause of concern for countries in the Americas *(14).* To advance toward universal access to health and universal health coverage, it is critical to expand access to health services for groups in conditions of vulnerability, prioritizing interventions that serve unmet needs. Countries face critical choices when prioritizing the expansion of services to ensure that population groups in situation of vulnerability are not left behind *(15).* Access to high-cost medicines can be lifesaving; at the same time, the cost of these products can dramatically increase the risk of people incurring catastrophic expenditures, and it can constitute a challenge to the sustainability of health systems.

Situation Analysis

8. More than 50% of all health-related trade corresponds to pharmaceuticals products. While 30% or more of health expenditure in developing nations goes to pharmaceuticals, 30% of the world's population lacks regular access to essential medicines *(16).* In 2010, Latin America and the Caribbean countries spent an average 7.65% of Gross Domestic Product in health, 1.7% of which went to medicines expenditures. Of total expenditure in medicines, 70% came from sources other than public spending *(17).*

9. Often, medicines and other health technologies represent the highest percentage of the cost of treatment and care. In Latin America and the Caribbean, antiretroviral medicines (ARVs) represented 75% of the cost of care for patients living with HIV/AIDS, reaching more than 90% in some instances. In general, a small number of high-cost medicines represents a large portion of the expenditures. In 2012, of all patients receiving ARVs, 71% used first-line ARVs while 27% and 2.5% used second and third-

[3] Refers to "the cost of treatment in relation to people's income".

line respectively. Yet, the cost for second and third-line amounted to 52% of total ARV expenditures *(18)*.

10. National regulatory authorities act as gatekeepers to ensure the safety, quality, and effectiveness of medicines and other health technologies and are critical in determining the rate of introduction of new products. Upon patent expiration, national regulatory authorities play a pivotal role in promoting competition by supporting efficient entry of quality generics and/or similar biotherapeutic products *(19)*. Strategies that promote prompt entry of competitor products within health systems result in considerable efficiencies without compromising the quality of care since competition tends to significantly reduce prices. In the United States, where generic sales account for over 60%, the Hatch-Waxman Act and Bolar exemption adopted in 1984 are considered critical for promoting quality generic entry *(20)*. In Latin America and the Caribbean, generic medicine sales amounted to only 7.8% in 2008 *(21)*. Due to lack of competition, off-patent generic medicines are sometimes marketed at elevated prices, however. Some countries have even experienced shortages of essential generic medicines *(22)* due to manufacturers leaving the market and/or because of manufacturing licenses that limit the commercialization of generic versions in certain markets *(23)*, forcing countries to opt for costly therapeutic substitutions.

11. High prices of new molecules are often justified due to the costs of research and development borne by the manufacturer. Yet, the precise research and development costs borne by the private sector are hard to establish and subject to controversy *(13)* since public spending in scientific research is often a major determinant for new discoveries *(24)*. Some recent initiatives address the lack of transparency in research and development costs. In the United States, a number of states are debating the introduction of legislation to improve research and development cost information, "in order to make pharmaceutical pricing as transparent as the pricing in other sectors of the health care industry" *(25)*. In addition, the Executive Board report 138/41 *(22)* states that "better understanding of research and development costs would enable a constructive dialogue on how to establish a fair and affordable price for medicines for children." Proposals to change the prevailing research and development funding model involving de-linkage of research and development costs and prices were documented by the WHO Consultative Expert Working Group report on Research and Development *(26)*.

12. The management of intellectual property rights from the public health perspective may limit the unnecessary extension of patent rights (evergreening) and support timely entry of multisource products. In addition, mechanisms such as Brazil's prior approval clause aim at improving the quality of patents that are granted. Trade-Related Aspects of Intellectual Property Rights flexibilities, including compulsory licensing (Art. 31) and exceptions to rights conferred (Art. 30), have also been used to ensure access to medicines. Canada issued compulsory licenses for Ciprofloxacin (2001) and TriAvir (2007) destined to Rwanda *(27)*. In 2007, Brazil issued a license for Efavirenz, and between 2010 and 2014, Ecuador issued licenses for Ritonavir, Acabavir+Lamivudine, Etoricoxib, Mycofenolate, Sunitinib, and Certolizumabs *(28)*.

13. Rapid diffusion, adoption, and inappropriate use of new products are major determinants of increasing health-care costs. Since 2011, the Regional Network of Health Technology Assessments for the Americas (RedETSA)[4] has promoted the use of HTA and other evidence-based analysis to inform decisions related to the adoption of new medical products within health systems. In 2015, 12 out of 28 countries that answered the survey had established HTA structures and 7 had adopted legislation requiring use of HTA in decision-making processes. Moreover, 92.9% of countries have national commissions for selection and drug and therapeutics committees, and have developed a national EML.

14. In large part, the demand for medicines is subject to decisions taken at the time of prescribing. It has been estimated that more than half of medicines worldwide are prescribed, dispensed or sold improperly *(29)* and that the responsible use of medicines would save US$ 500 billion[5] globally *(30).* More importantly, the inadequate prescribing, dispensing, and use of medicines and other health technologies is critical for substandard treatment outcomes. Only 42.9% of countries declared in 2015 having adopted standards and procedures for developing CPGs.

15. A number of Member States are ensuring access to a number of high-cost medicines and other health technologies using public funding with or without dedicated mechanisms for the financing. The *Fondo Nacional de Recursos* (Uruguay) *(31),* the *Componente Especializado da Assistência Farmacêutica* (Brazil), the *Programa de Medicamentos de Alto Costo* (Dominican Republic), and the recently adopted *Ricarte Soto* law (Chile) are notable examples.

16. National authorities can influence prices of medicines and other health technologies. National reimbursement and pricing policies may impact affordability, availability, and the price of medicines. The lack of access to reliable pricing information poses a challenge when opting and assessing these policies and their outcomes. Additionally, the mechanism by which medicines and other health technologies are procured may have substantial impact on price. Procurement practices that favor competition and concentrate public purchasing power tend to be effective in lowering prices. By consolidating demand across the public sector, national pooled procurement mechanisms are improving their negotiation and bargaining power and pricing outcomes. Such is the case of the *Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud* in Mexico *(32).*

17. Similar results have been observed when the demand is pooled internationally. The most prominent examples are the PAHO Revolving Fund for Vaccines, as well as the Regional Revolving Fund for Strategic Public Health Supplies also known as the Strategic Fund. Since 2000, the Strategic Fund has been providing technical cooperation

[4] RedETSA is comprised of representatives from the ministries of health, regulatory agencies, HTA agencies, PAHO/WHO collaborating centers, and non-profit educational and research institutions dedicated to promote HTA to inform decision-making.

[5] Unless otherwise indicated, all monetary figures in this report are expressed in United States dollars.

to Member States to ensure access to quality, safe and effective medicines, diagnostics and insecticides, of limited availability, presenting particular challenges to countries in supply and procurement, and/or high cost: the selection of medical products[6] for inclusion in the Strategic Fund is evidence based, supports the concept of essential medicines, and aims to improve access to products with limited availability, difficult to procure at the national level, or of high cost such as medicines to treat communicable diseases. By achieving economies of scale and promoting competition, the Strategic Fund contributes to the availability, quality, and affordability of strategic public health supplies *(33)*. As of March 2016, 27 Member States had signed participation agreements with the Strategic Fund.

18. Another strategy used by Member States on a number of occasions is joint price negotiations. In 2015, MERCOSUR and associated countries jointly negotiated agreements directly with manufacturers for ARV and Hepatitis C medicines. PAHO supported the mechanism with technical advice and enabling procurement through the Strategic Fund. The participating countries achieved cost savings of $20 million in the procurement of one of the medicines included in the negotiation first round *(34)*. With the support of the Central American Integration System and PAHO, Central American countries have also executed multicountry negotiations resulting in significant efficiencies for participating countries *(35)*.

19. In the Americas, 20 of the 35 Member States have the enjoyment of the right to the highest attainable standard in health incorporated in their Constitutions and other legal provisions.[7] Adequate, strong, legal, and regulatory frameworks promote and protect access to health including from the perspective of the right to health where nationally recognized, and promoting the right to the enjoyment of the highest attainable standard of health *(5)*. Demand for medical products is increasing and ensuring access to medicines and other health technologies constitutes a challenge for health systems. In some cases, even though medicines and other health technologies have been shown to be cost-effective, the system does not make them available to all citizens in a manner that is equitable and affordable. In these cases, one option has been to turn to the judicial system to enforce access to health technologies. An example of this was the request for precautionary measures submitted to the Inter-American Commission on Human Rights (IACHR) that guaranteed access to antiretroviral medicines in 10 countries of the Region.[8] *(3, 36)*

[6] The list of strategic health supplies in the Strategic Fund include products for HIV/AIDS, tuberculosis, malaria, and neglected infectious diseases; diagnostics and vector control commodities and medicines for noncommunicable diseases (cancer, cardiovascular and respiratory diseases, and diabetes) can be accessed at http://www.paho.org/strategicfund.

[7] Bolivia, Brazil, Colombia, Chile, Cuba, Dominican Republic, Ecuador, El Salvador, Guatemala, Guyana, Haiti, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Suriname, Uruguay, and Venezuela.

[8] For more information on the measures adopted by the Inter-American Commission on Human Rights (IACHR) with regard to access to antiretroviral drugs in Bolivia, Colombia, Dominican Republic, Ecuador, Guatemala, Honduras, Nicaragua, and Peru, see the IACHR Annual Report 2002. With regard to measures adopted for Chile and El Salvador, see the IACHR Annual Report 2001. Reports available at: www.cidh.org/annual.eng.htm.

20. In other cases, the unsatisfied demand for high-cost products has also resulted in legal actions or "judicialization", where individuals or patient groups have reverted, as mentioned above, to the judicial system to ensure access to these products. Judicialization may enable individuals to access products other than those expressly offered or recommended by the health system. While constituting an important mechanism to ensure access to medicines, a 2013 study conducted in 3 countries showed that most products involved in such litigations were not part of the national EML *(37).*

Proposal

21. Improving access to and rational use of quality, safe, and cost-effective medicines and other health technologies including those of high cost, is necessary to achieve universal health. Member States may provide access to high-cost medicines and other health technologies through established or dedicated mechanisms, and in a manner that is coherent with context and capacity of the health system. To ensure the most efficient and equitable outcomes, Member States can leverage the following policy options:

Policy Option A: Comprehensive national health and pharmaceutical and other health technology policies

22. Comprehensive national policies and/or strategies that contemplate health system needs and the entire product life-cycle—from research and development to quality assurance and use, including prescribing and dispensing—are critical to ensure access to safe, quality, and cost-effective medicines and other strategic health technologies. These policies and strategies should balance public health needs with the economic and social development objectives by promoting collaboration with the science and technology and industrial sectors and by stimulating research and development models that address pressing health needs and incentivize, when possible, the de-linkage of research and development costs and price of health products *(38).*

23. Countries should strengthen health information systems to monitor the quality, provision, access, and use of medical products within health systems. These systems can also support decision-making for the introduction of new medicines and other health technologies based on health systems' needs, through participatory and transparent mechanisms, and promote good governance.

24. Financing and financial protection mechanisms should prevent financial hardship associated with out-of-pocket expenditures, and support the progressive expansion of health services while ensuring sustainability of the system. Improved transparency and accountability in the allocation of resources for medicines and other health technologies will result in more effective and efficient health systems.

25. The adoption of an explicit list of medicines and other health technologies that addresses critical priorities and is progressively expanded can promote efficiency and equity. An appropriate legal and regulatory framework combined with quality

information and collaboration, as appropriate, with the legislative judicial sectors[9] can reduce judicial actions taken to ensure access to costly health technologies of little or no public health value; in addition, strengthening regulatory capacities should prevent the introduction of ineffective medicines.

Policy Option B: Strategies that improve transparency and knowledge for decision-making

26. The selection, evaluation, adoption, and use of medicines and other health technologies should be based on health priorities and undergo rigorous assessment based on the best available scientific evidence taking into account the social, intercultural, equity, gender, and ethical implications and the health systems context. The use of HTA can greatly contribute to the managed introduction of new health technologies, expanding their use and/or making disinvestment decisions. The value of these methods, however, is only as strong as the quality of the effectiveness data and the cost estimations that are input in the assessments. Thoroughly assessing the cost-effectiveness of a new health technology requires a comparative analysis of standard and new treatments considering all incurred and averted costs. Thus, countries should strengthen capacities to measure health-care costs and produce quality scientific evidence. Moreover, they should monitor health products given the limited strength of the evidence that often exists when these are introduced into the health system.

27. Policies that promote price disclosure and better understanding of costs and price structure comprising research and development, distribution, taxes and retail costs, and markups will support product selection, pricing strategies, and regulations. Similarly, countries should establish and promote mechanisms that improve price information sharing among countries and within different actors in a country. National and multicountry price databases are valuable decision-making tools. Moreover, supply chain transparency and good procurement practices contribute to the efficiency of the system.

Policy Option C: Strategies that improve pricing outcomes and efficiency

28. Improving the affordability of medical products will facilitate timely and equitable access. Promoting an environment that generates competition is strategic to this end since access to quality, lower-cost alternatives provides efficiency without compromising quality of care. Policies that promote the uptake of multisource products need to impact the entire product life-cycle from market entry to prescription, dispensing, and use. They require the management of intellectual property rights from a public health

[9] PAHO Directing Council has urged Member States, as appropriate, taking into account their national context, priorities, and financial and budgetary capacities, to strengthen the technical capability of the health authority to facilitate coordination and collaboration with the legislative branch and other actors, including the identification and review of legal gaps and conflicts. See the PAHO Strategy on Health-Related Law (2015), available at: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=31293&Itemid=270&lang=en

perspective, the promotion of therapeutic and generic replacement, a regulatory framework for rapid introduction of quality alternatives, and adaptive procurement mechanisms.

29. The strengthening of capacities to manage intellectual property rights from a public health perspective should improve the quality of patents granted and prevent unjustified perpetuation of market exclusivity. In cases of a national emergency or other circumstances of extreme urgency, health systems should ensure the proper and timely use of flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), ratified by the Doha Declaration on TRIPS and Public Health as well as WHO's global strategy on public health, innovation and intellectual property *(38)*. Additionally, it is important to weigh and monitor the potential impact that international trade agreements may have on the access to health products. Promoting active participation of health representatives in intellectual property-related and trade negotiations may help reflect public health perspectives within such negotiations *(38).*

30. While there is not a one-size-fits-all policy, the choice of the strategy that countries choose to influence medicine prices needs to reflect the context of the health system. WHO Guidelines on country Pharmaceutical Pricing Policies illustrates some of the options available *(39).* The choice of procurement mechanism also influences prices. Open international tenders promote competition and secure lower prices when compared with other procurement methods. For sole and/or limited source products, national and international initiatives that limit fragmentation by pooling demand across different sub-systems and/or across countries coupled with transparent open negotiations are viable options to improve pricing outcomes. Availing of regional pooled procurement mechanisms such as the Strategic Fund through Regional commitments and cooperation among countries can reduce market fragmentation, improve the ability of countries to negotiate more affordable and equitable prices, and market transparency.

Policy Option D: Strategies that promote the rational use of medicines and other health technologies

31. To improve health-care effectiveness and efficiency, countries should adopt integrated strategies for the assessment, selection, adoption, and use of medicines and other health technologies. Evidence-informed and culturally acceptable principles remain critical for the rational use of medicines and other health technologies.[10]

32. Independent unbiased information is necessary for the sound selection, incorporation, prescription, and use of medicines and health technologies. The use of the Declaration of Conflict of Interest should be a common practice for selection bodies. The prevention of the dissemination of biased information that can wrongly influence prescription and/or use patterns should be prevented through the regulation of the

[10] Guidelines for national strategies are provided in the Pan American Sanitary Bureau "Strategy for the rational use of medicines and other health technologies" document.

pharmaceutical marketing and promotion, facilitating access to evidence-based information material for stakeholders.

33. Health systems need to encourage the use of the most cost-effective treatments and prevent the replacement of effective lower-cost medicines and other health technologies with new more costly products of little or no added value. Ensuring availability of lower price products and preventing excessive and wasteful use of high-cost ones is critical. Demand of medical products is mostly in the hands of prescribers, hence, the adoption of comprehensive incentives directed at prescribers may help improve prescription quality and prevent excessive and/or unnecessary use of costly options.

Action by the Executive Committee

34. The Executive Committee is requested to review the information provided in this document and to consider adopting the resolution presented in Annex A.

Annexes

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Pan American Health Organization
World Health Organization
REGIONAL OFFICE FOR THE Americas

158th SESSION OF THE EXECUTIVE COMMITTEE

Washington, D.C., USA, 20-24 June 2016

CE158/15
Annex A
Original: English

PROPOSED RESOLUTION

ACCESS AND RATIONAL USE OF STRATEGIC AND HIGH-COST MEDICINES AND OTHER HEALTH TECHNOLOGIES

THE 158th SESSION OF THE EXECUTIVE COMMITTEE,

Having reviewed the proposed policy document *Access and Rational Use of Strategic and High-Cost Medicines and Other Health Technologies* (Document CE158/15),

RESOLVES:

To recommend that the Directing Council adopt a resolution along the following lines:

ACCESS AND RATIONAL USE OF STRATEGIC AND HIGH-COST MEDICINES AND OTHER HEALTH TECHNOLOGIES

THE 55th DIRECTING COUNCIL,

(PP1) Having reviewed the policy document *Access and Rational Use of Strategic and High-Cost Medicines and Other Health Technologies* (Document CD55/__);

(PP2) Considering that the Constitution of the World Health Organization (WHO) establishes as one of its basic principles that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social condition;"

(PP3) Recalling Resolution CD53.R14 on Universal Access to Health and Universal Health Coverage, and United Nations Resolution A/RES/70/1 adopting the Agenda 2030 for Sustainable Development including Goal number 3, Ensure healthy lives and promote well-being for all at all ages;

(PP4) Recognizing that improving equitable access to and the rational use of medicines and other health technologies is necessary to achieve universal access to health and universal health coverage and the achievement of the Sustainable Development Goals;

(PP5) Taking into consideration that the adoption and implementation of comprehensive policies, laws, regulations, and strategies are necessary to improve access to strategic and high-cost medicines and other health technologies, and the quality of health services and health outcomes, while ensuring the sustainability of health systems;

(PP6) Taking into account that a number of high-cost medicines and other health technologies are now considered essential and can significantly improve quality of life and health outcomes when used in accordance with evidence informed clinical practice guidelines;

(PP7) Recognizing that the rapid diffusion and adoption of new and costly medicines and other health technologies is a major determinant of the increasing costs of health care and the sustainability of health systems, and that many high-cost medicines and other health technologies incorporated into health systems do not provide significant added value as they displace effective lower-cost treatments;

(PP8) Recognizing the need to improve access through comprehensive approaches that focus on improving availability, affordability, and rational use within health systems and guidance; provided by the Pan American Sanitary Bureau's strategy for the rational use of medicines and other health technologies;

(PP9) Recognizing the challenges currently being faced by Member States in ensuring access and rational use of high-cost medicines and other health technologies,

RESOLVES:

(OP)1. To urge Member States to:

a) adopt comprehensive national policies and/or strategies together with legal and regulatory framework to improve access to medicines and other health technologies that contemplate the needs of health systems and the overall life-cycle of the medical products from research and development to quality assurance and use, including prescribing and dispensing, and that disincentivize spurious demands for costly ineffective medicines and health technologies;

b) strengthen institutions, mechanisms, and processes to promote good governance, quality, effectiveness, and safety of medicines and other health technologies, including regulatory capacity and promoting transparency and accountability in the allocation of resources for medicines and other health technologies to seek effectiveness and efficiency of health systems;

c) progressively expand the explicit lists of medicines and other health technologies to meet health needs, using evidence-informed approaches and ensure adequate financing and financial protection mechanisms to ensure access, to prevent financial hardship and promote sustainability of the health system;

d) improve transparency and information in the pharmaceutical sector and health system, including in the determination of research and development costs, pricing and price structures, supply chain management and procurement practices to support the assessment of pricing outcomes and the adoption of pricing strategies coherent with the context of the national health system and, improve decision-making, avoid waste and improve affordability of medicines and other health technologies;

e) strengthen institutional capacities for evidence-informed decision-making and national bodies responsible for developing essential medicines lists; improve capacity to generate high-quality evidence, quantify the cost of care and produce high-quality health technology assessments and other evidence-based approaches to evaluate the cost-effectiveness of new technologies prior to their inclusion in health systems with particular attention of those considered high cost;

f) promote competition through comprehensive strategies that may include the management of intellectual property rights from a public health perspective, the establishment of incentives and regulations that permit the prompt entry and uptake of quality multisource medicines and/or therapeutic equivalents, and the adoption of procurement mechanisms that stimulate competition and limit fragmentation by pooling the demand across different national sub-systems and/or across countries to improve the bargaining power of the health system and pricing outcomes such as the PAHO Revolving Regional Fund for Strategic Public Health Supplies (the PAHO Strategic Fund);

g) adopt effective strategies to improve the affordability of single source or limited source products such as, but not limited to, national and international open price negotiations, reimbursement, and pricing policies and strategies, and when appropriate, the use of flexibilities contemplated in the Agreement on Trade-Related Aspects of Intellectual Property Rights;

h) adopt measures to promote access to independent and unbiased information on medical products for health professionals and the general population in order to promote the rational use of medicines and other health technologies and to improve prescribing and dispensing according to the best evidence available; and monitor the safe use and effectiveness of these products through strong pharmacovigilance/technovigilance systems;

i) recognize the role of prescribers in the decisions relating to treatment options, provide adequate support to improve prescribing practices through the use of clinical practice guidelines, incentives, prescription support, educational strategies and regulations to address the conflicts of interest between prescribers and medical products manufacturers.

(OP)2. To request the Director to:

a) support Member States in the development of comprehensive medicines and health technology policies and legal frameworks that promote access to essential and strategic medicines and other health technologies including those considered high cost;

b) support Member States in the development, implementation, and/or review of national legal and regulatory frameworks, policies, and other provisions that permit the prompt entry and uptake of quality multisource medicines and/or therapeutic equivalents through comprehensive strategies, including the management of intellectual property rights from a public health perspective and report on technical, procedural, legal barriers that undermine competition for medicines and health technologies;

c) support Member States in building capacities and adopting strategies to improve the selection and rational use of medicines and other health technologies based on health technology assessments and other evidence-based approaches to ensure their effective use, and improve health outcomes and efficiencies;

d) promote cooperation and sharing of information on medicines and other health technologies' cost-effectiveness, supply chain issues and pricing best practices, among others, through PAHO's available channels and networks, and synthesize and report progress made by Member States in key areas;

e) continue to strengthen PAHO Strategic Fund to provide ongoing support to Member States on all aspects related to making quality medicines and health technologies available and more affordable, including providing a platform for supporting participating Member States in the pooling, negotiation and procurement of high-cost single source and limited source medicines.

Pan American Health Organization

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CE158/15
Annex B

Report on the Financial and Administrative Implications of the Proposed Resolution for PASB

1. Agenda item: 4.5 - Access and Rational Use of Strategic and High-Cost Medicines and Other Health Technologies

2. Linkage to PAHO Program and Budget 2016-2017:

a) Categories: 4 - Health Systems

b) Program areas and outcomes:
Program Area 4.3 - Access to Medical Products and Strengthening of Regulatory Capacity

Outcome 4.3 - Improved access to and rational use of safe, effective, and quality medicines, medical products, and health technologies.

3. Financial implications:

a) Total estimated cost for implementation over the lifecycle of the resolution (including staff and activities):

While the implementation of this resolution should be ongoing and embedded in the technical cooperation under 4.3 and related areas, the expectation is that an additional US$ 1,750,000 will be required to scale up the technical cooperation from 2016-2021.

b) Estimated cost for the 2016-2017 biennium (including staff and activities):

US$ 700,000

c) Of the estimated cost noted in *b),* what can be subsumed under existing programmed activities?

As mentioned before, we are only including additional costs.

4. Administrative implications:

a) Indicate the levels of the Organization at which the work will be undertaken:

The Unit of Medicines and Health Technologies within the Department of Health Systems and Services, is the responsible for this agenda item. Nonetheless, it is essential to mention that the Department of Procurement's Strategic Fund Unit will play a critical role in its implementation. In addition, other units within the Departments of Health Systems and Services, Communicable Diseases and Health Analysis, Noncommunicable Diseases and Mental Health, and Family, Gender and Life Course, as well as the Office of the Legal Counsel will play essential roles in the deployment.

b) Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):

One additional P2-P3 staff to support scale-up and coordination among current personnel providing technical cooperation in this area with expertise in pharmaceutical pricing, rational use/HTA, and/or policies.

c) Time frames (indicate broad time frames for the implementation and evaluation):

2016-2021: implementation phase

2021: evaluation phase

2022: report to the Governing Bodies

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. Agenda item: 4.5 - Access and Rational Use of Strategic and High-Cost Medicines and Other Health Technologies

2. Responsible unit: Health Systems and Services, Medicines and Health Technologies (HSS/MT)

3. Preparing officer: Dr. Analía Porrás, Chief, Medicines and Health Technologies

4. Link between Agenda item and Health Agenda for the Americas 2008-2017:

Items 38, 45, 46, 47, 48, 50, 70.

To increase access to quality, safe, and effective medicines, medical supplies and health technologies promoting the rational use of medicines, strengthening the subregional procurement mechanisms, reducing tariff barriers applied to medicines and health technologies ensuring financial protection and sustainable financing.

5. Link between Agenda item and the PAHO Strategic Plan 2014-2019:

Program area 4.3, Access to Medical Products and Strengthening of Regulatory Capacity

Furthermore, this agenda item will support the achievement of the objectives related to reducing the burden of communicable diseases such as HIV and chronic noncommunicable diseases.

6. List of collaborating centers and national institutions linked to this Agenda item:

National regulatory authorities, in particular those considered of reference by Resolution CD50.R9 (2010), ministries of health, and PAHO/WHO Collaborating Centers as follows:

University of Ottawa, Bruyère Research Institute, Centre for Global Health: PAHO/WHO Collaborating Center for Knowledge Translation and Health Technology Assessment in Health; Universidade Federal de Santa Catarina (UFSC): PAHO/WHO Collaborating Center for Management Technology in Health; Centro Nacional de Excelencia Tecnológica en Salud (CENETEC): PAHO / WHO Collaborating Center on Health Technology; Instituto de Efectividad Clínica y Sanitaria (IECS): Collaborating Centers Unit of Medicines and Health Technologies; Núcleo de Assistência Farmacêutica Fundação Oswaldo Cruz: WHO Collaborating Center for Pharmaceutical Policies; National University of La Plata: WHO Collaborating Center on the Rational Use of Medicines.

7. Best practices in this area and examples from countries within the Region of the Americas:

There are several initiatives in the Region to improve access and rational use of high-cost medicines. The Ricardo Soto Law (CHL), Fondo Nacional de Recursos (URY), Componente Especializado da Assistência Farmacêutica (BRA), Programa de Medicamentos de Alto Costo (DOM), Comisión Coordinadora para la Negociación de Precios de Medicamentos y otros Insumos para la Salud (MEX), and the joint negotiation in MERCOSUR, among others.

8. Financial implications of this Agenda item:

Implementation of this agenda item will be embedded within the 4.3 program of work and thus will require additional funding to scale up the technical cooperation, in particular, for improving rational use of medicines and health technologies. Thus, the additional cost for 2016-2021 is expected to be in the order of US$ 1,750,000.

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